PAPAIN

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

› Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.
› The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 10, 2012

Proper name(s)

Papain (IUBMB 2000)

Common name(s)

Papain (IUBMB 2000)

Source material(s)

› Fruit of papaya (*Carica papaya* L. (Caricaceae)) (Merck 2012; USDA 2011; Morton 1987)
› Leaf of papaya (*Carica papaya* L. (Caricaceae)) (Merck 2012; USDA 2011; Morton 1987)

Route(s) of administration

Oral

Dosage form(s)

› The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
› This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
**Use(s) or Purpose(s)**

Statement(s) to the effect of:

Digestive enzyme (Merck 2012)

**Dose(s)**

**Subpopulation(s)**

Adults (≥ 19 years)

**Quantity(ies)**

Dose information must include the quantities of both the enzyme preparation and its enzymatic activity:

- Providing up to $1.2 \times 10^3$ mg per day enzyme preparation of the latex from the leaf and/or unripe fruit of papaya; not to exceed 400 mg per dose (Dörr and Herrman 2007; Martin et al. 2002; Dale et al. 2001; Morton 1987); and
- Enzyme activity providing up to $7.2 \times 10^6$ FCC PU per day; not to exceed $2.4 \times 10^6$ FCC PU per dose (Martin et al. 2002; Dale et al. 2001).

**Notes**

- One papain unit (PU) is defined as that quantity of enzyme that liberates the equivalent of 1 μg of tyrosine per hour under the conditions of the assay (FCC 8).
- One FCC papain unit is approximately equivalent to one USP papain unit (1 FCC PU ≈ 1 USP PU).
- For multi-ingredient products containing both papain and bromelain (fruit and/or stem), the combined proteolytic activity should not exceed the maximum proteolytic activity of $1.3 \times 10^8$ FCC PU per day (as per the NHPD Bromelain, Stem monograph).

**Directions for use**

Take with food/a meal.

**Duration of use**

For prolonged use, consult a health care practitioner.

**Risk information**

Statement(s) to the effect of:

**Caution(s) and warning(s)**

- If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
If you have a gastrointestinal lesion/ ulcer, are taking an anticoagulant/ blood thinner or an anti-inflammatory, or are having surgery, consult a health care practitioner prior to use (Martindale 2011).

If you have allergy to latex or fruits (such as avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato), consult a health care practitioner prior to use (US FDA 2008; APhA 2006; Brehler et al. 1997).

**Contraindication(s)**

No statement required.

**Known adverse reaction(s)**

Hypersensitivity/allergy has been known to occur, in which case discontinue use (HC 2011; Martindale 2011; US FDA 2008).

**Non-medicinal ingredients**

Must be chosen from the current NHPD Natural Health Products Ingredients Database and must meet the limitations outlined in the database.

**Specifications**

- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
- Details of the manufacturing of the enzyme at the raw material stage should include fermentation medium and the isolation process of the medicinal ingredient.
- The specifications must include testing for enzymatic activity of the medicinal ingredient at appropriate stages of formulation and manufacturing using the assay outlined in the current Food Chemicals Codex (FCC): PLANT PROTEOLYTIC ACTIVITY.
- The medicinal ingredient may comply with the specifications outlined in the current United States Pharmacopeia (USP): Papain.
- Where published methods are not suitable for use, manufacturers will use due diligence to ensure that the enzymes remain active to the end of their shelf life indicated on the product label.

**References cited**


References reviewed